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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 120806310-3555-02]

RIN 0694-AF76

Implementation of the Understandings Reached at the 2012 Australia Group (AG) Plenary Meeting and the 2012 AG Intersessional Decisions; Changes to Select Agent Controls -- Correction

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule; correcting amendment.

SUMMARY: The Bureau of Industry and Security (BIS) published a final rule in the Federal Register on Wednesday, June 5, 2013 (78 FR 33692), that amended the Export Administration Regulations (EAR) to implement the understandings reached at the June 2012 plenary meeting of

the Australia Group (AG) and the 2012 AG intersessional decisions. That final rule also amended the EAR to reflect recent changes to the controls maintained by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, on the possession, use, and transfer of select biological agents within the United States. The preamble of that final rule contained an error in its description of the amendments to Export Control Classification Number (ECCN) 1C351 that were based on the understandings reached at the 2012 AG Plenary. The preamble also contained an error in its description of the amendments to ECCN 2B352 that were based on the 2012 AG intersessional decisions. In addition, that final rule contained errors affecting the control language in ECCN 2B352, which controls specified equipment capable of use in handling biological materials. This document corrects these errors.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Elizabeth Sangine, Director, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482-3343.

SUPPLEMENTARY INFORMATION:

Background

On June 5, 2013, the final rule “Implementation of the Understandings Reached at the 2012 Australia Group (AG) Plenary Meeting and the 2012 AG Intersessional Decisions; Changes to Select Agent Controls” was published in the Federal Register (78 FR 33692). In the preamble of that final rule, the discussion of the amendments to ECCN 1C351 erroneously indicated that the bacterium “*Coxiella burnetii*” was previously controlled under ECCN 1C351.c.11 when, in fact, this bacterium was previously controlled under ECCN 1C351.c.10 and is now controlled under 1C351.c.13, based on the amendments contained that final rule. Instead, prior to the publication of that final rule, ECCN 1C351.c.11 controlled “Enterohaemorrhagic *Escherichia coli*, serotype O157 and other verotoxin producing serotypes.” As a result of the amendments made by that final rule, these bacteria are now controlled under ECCN 1C351.c.17, with the control language having been clarified to read “Shiga toxin producing *Escherichia coli* (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups.”

The preamble of that final rule also contained an error in its description of the amendments to ECCN 2B352. Specifically, in the description of the technical characteristics of the spray-drying equipment now controlled under ECCN 2B352.f, the preamble mistakenly referred to “a typical mean product particles size” when it should have said “a typical mean product particle size,” consistent with the control language in ECCN 2B352.f.2.

In addition, that final rule amended ECCN 2B352, under the “Items” paragraph in the List of Items Controlled, by redesignating paragraphs f. through h. as paragraphs g. through i.,

respectively, and adding a new paragraph f. to control specified spray drying equipment capable of drying toxins or pathogenic microorganisms. However, that final rule did not make the necessary conforming changes, in ECCN 2B352.i.3 and Technical Note 2 to ECCN 2B352, to reflect the redesignation of 2B352.h (specified spraying or fogging systems and components therefor) as 2B352.i.

This rule makes these conforming changes, as follows. First, in ECCN 2B352.i.3, the phrase “as specified in paragraphs h.1 and h.2 of this ECCN” is revised to read, “as specified in paragraphs i.1 and i.2 of this ECCN.” Second, in Technical Note 2 to ECCN 2B352, the phrase “as specified in 2B352.h” is revised to read, “as specified in 2B352.i.” These conforming changes do not affect either the scope of the EAR controls that apply to equipment controlled under ECCN 2B352 or the specific equipment that is subject to these EAR controls.

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 15, 2012, 77 FR 49699 (August 16, 2012), has continued the EAR in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains a collection of information subject to the requirements of the PRA. This collection has been approved by OMB under Control Number 0694-0088 (Multi-Purpose Application), which carries a burden hour estimate of 58 minutes to prepare and submit form BIS-748. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget (OMB), and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 14th Street and Pennsylvania Avenue, N.W. Room 6622, Washington, DC 20230.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). The changes contained in this rule are non-substantive technical corrections of a previously published rule that has already been exempted from notice and comment and delay in effective date provisions, because the content of the June 5, 2013, final rule involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). The corrections contained in this final rule are essential to ensuring the accurate and complete implementation of the June 5, 2013, final rule.

Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are not applicable. Therefore, this regulation is issued in final form.

List of Subjects

15 CFR Part 774

Exports, Reporting and recordkeeping requirements

For the reasons stated in the preamble, part 774 of the Export Administration Regulations (15 CFR parts 730-774) is amended as follows:

PART 774 - [AMENDED]

1. The authority citation for 15 CFR Part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*, 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2012, 77 FR 49699 (August 16, 2012).

Supplement No. 1 to Part 774 - [Amended]

2. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2 -- Materials Processing, ECCN 2B352 is amended under the “*Items*” paragraph in the List of Items

Controlled section by revising paragraph i.3 and Technical Note 2 that follows paragraph i. to read as follows:

2B352 Equipment capable of use in handling biological materials, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: * * *

Related Controls: * * *

Related Definitions: * * *

Items:

* * * * *

i. * * *

i.3. Aerosol generating units specially designed for fitting to the systems as specified in

paragraphs i.1 and i.2 of this ECCN.

Technical Notes:

1. * * *

2. This ECCN does not control spraying or fogging systems and components, as specified in 2B352.i., that are demonstrated not to be capable of delivering biological agents in the form of infectious aerosols.

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DATED: June 27, 2013.

Bernard Kritzer

Director

Office of Exporter Services